

EXHIBIT 6

Archived Content

The content on this page is provided for reference purposes only. This content has not been altered or updated since it was archived.

Search Archive

[Home Inspections, Compliance, Enforcement, and Criminal Investigations](#) [Compliance Actions and Activities](#) [Warning Letters 2011](#)

Inspections, Compliance, Enforcement, and Criminal Investigations

Island Desserts LLC 10/5/11



Department of Health and Human Services

Public Health Service
Food and Drug Administration
New England District
One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 587-7500
FAX: (781) 587-7556

WARNING LETTER

CMS #206995

October 5, 2011

VIA UPS OVERNIGHT MAIL

Robert F. Leavitt, President
Island Desserts, LLC
24 Walpole Park South
Walpole, Massachusetts 02081

Dear Mr. Leavitt:

The U.S. Food and Drug Administration (FDA) inspected your food manufacturing facility, located at 24 Walpole Park South, Walpole, Massachusetts, on June 16, 17, 20, 24 and 30, 2011. Our investigation found serious violations of the FDA's Current Good Manufacturing Practice (CGMP) regulations for manufacturing, packing, or holding human food (21 CFR Part 110). These violations cause the products manufactured in your facility, which operates under the name Pastry Art, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342 (a)(4)] in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. In addition, we have reviewed the labels for your Chocolate Cherry Biscotti and Traditional Almond Biscotti products and have determined that they are misbranded within the meaning of Section 403 of the Act [21 U.S.C. § 343]. You may find the FD&C Act and FDA's regulations through links on FDA's home page at www.fda.gov.

CGMP Violations

Our inspection of your facility revealed the following violations of the CGMP regulation (21 CFR Part 110):

1. Your firm failed to handle work-in-process in a manner that protects against contamination, as required by 21 CFR 110.80(b)(5). The production procedures your firm uses could cause products that contain nut allergens to contaminate products that do not contain nut allergens. Specifically:

- Non nut-containing pasticciotti were placed on a tray with scattered pieces of pistachios and placed next to nut-containing cannolis with pistachios.
- Non nut-containing chocolate cherry biscotti were placed on a tray with nut-containing almond biscotti.
- An employee was observed slicing nut-containing cappuccino hazelnut biscotti prior to slicing non nut-containing chocolate cherry biscotti, without first changing gloves.
- An employee was observed handling crushed pistachios with gloved hands and subsequently touching the inside of a pastry bag used to fill non nut-containing éclairs.
- Uncovered nut-containing products---such as mixed nut tarts, almond biscotti and pecan tarts---were stored next to or above uncovered non nut-containing foods such as chocolate mousse, lemon tart, raspberry tart, éclair, tiramisu miniature desserts, chocolate cherry biscotti, and tart bases.

Manufacturers are responsible for ensuring that their products are not adulterated as a result of contamination with allergens. When allergens that are not specifically formulated in a food are identified as likely to occur in the food because of manufacturing practices, manufacturers should identify and implement controls to reduce or prevent allergen cross-contact. Examples of preventive measures include production scheduling, dedicated equipment for production runs of products for which cross-contact is a concern, and proper cleaning.

We have received your response to the FDA 483, dated July 8, 2011. Although you stated that you planned to address the procedures that could lead to cross-contamination of allergens in products without allergenic ingredients, your response is inadequate because you failed to provide detailed information and documentation that would assist us in evaluating whether you have implemented the necessary corrections. For example, you stated that your plan will eliminate "most" allergens from the non-allergen part of the facility. However, you did not explain what "most" means. You reported that you are going to segregate portions of the facility. However, you failed to describe what portions of the facility you are planning on segregating. Although you represented that you will have a common area and have a wash down procedure, you failed to describe this wash down procedure and steps you are going to take in order to prevent cross-contamination in these common areas. Further, you suggested that you would provide employee training on production processes, but you did not describe the training that you plan to provide to your employees or the compliance monitoring procedures.

We also note that you stated in your response that you will develop labeling to "include information about potential allergen cross contamination." Precautionary labeling, however, is not a substitute for adherence to good manufacturing practices.

2. You failed to maintain gloves that are used in food handling in an intact, clean, and sanitary condition, as required by 21 CFR 110.10(b)(5). Specifically, employees were observed wearing torn gloves during finished food production.

Misbranding Violations

Our review of your labels found that some of your products are misbranded under section 403 of the Act, 21 U.S.C. § 343:

1. Your Chocolate Cherry Biscotti and Traditional Almond Biscotti products are misbranded within the meaning of section 403(w) of the Act [21 U.S.C. § 343(w)] in that the labels fail to declare the major food allergens present in the products.

Section 201(qq) of the Act [21 U.S.C. § 321 (qq)] defines as "major food allergens" milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils. A food is misbranded if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either:

- The word "contains," followed by the name of the food source from which the major food allergen is derived, is printed immediately after or adjacent to the list of ingredients. See section 403(w)(1)(A) of the Act [21 U.S.C. § 343(w)(1)(A)]; or

- The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source from which the major food allergen is derived, (e.g. "flour (wheat)"), except that the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source or the name of the food source appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of an ingredient that is not a major food allergen). See section 403(w)(1)(B) of the Act [21 U.S.C. § 343(w)(1)(B)].

For example, your Chocolate Cherry Biscotti is made with bread flour, which, according to the label for the bread flour, contains wheat. Your Chocolate Cherry Biscotti is also made with unsalted butter and eggs. Wheat, milk and eggs are major food allergens; however, your label fails to declare the allergens wheat, milk and egg. Your Traditional Almond Biscotti is also made with bread flour, unsalted butter, and eggs, as well as whole almonds (which are tree nuts). Wheat, milk, eggs, and tree nuts are major food allergens; however, your label fails to declare the allergens wheat, milk, egg, and almond.

2. Your Chocolate Cherry Biscotti and Traditional Almond Biscotti products are misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)] because the labeling fails to declare a complete list of all the ingredients by common or usual name in descending order of predominance by weight as well as all sub-ingredients, as required by 21 CFR 101.4(a)(1). For example, your Chocolate Cherry Biscotti and Traditional Almond Biscotti are made with two or more ingredients; however, your label fails to include a declaration of ingredients.
3. Your Chocolate Cherry Biscotti and Traditional Almond Biscotti products are misbranded within the meaning of section 403(e)(1) [21 U.S.C. § 343(e)(1)], in that the packages do not contain the name and place of business of the manufacturer, packer, or distributor. For example, your labels for your Chocolate Cherry and Traditional Almond Biscotti products bear no such information.
4. Your Chocolate Cherry Biscotti and Traditional Almond Biscotti products are misbranded within the meaning of section 403(e)(2) of the Act [21 U.S.C. § 343(e)(2)] in that the packages fail to bear an accurate statement of the net quantity of contents in terms of weight, measure, or numerical count. When the declaration of quantity of contents by numerical count does not give adequate information as to the quantity of food in the package, the declaration must be combined with a statement of weight, measure, or size of the individual units of the food as will provide such information [21 CFR 101.105(c)]. The product labels for your Chocolate Cherry and Traditional Almond Biscotti state "Qty 24." This does not adequately describe the amount of food in the package because the weight, measure, or size of the individual pieces of biscotti can vary.

The above violations are not intended to be an all-inclusive list of the violations at your facility or with your product labeling. You are responsible for ensuring that your products are in compliance with the applicable statutes and regulations administered by the FDA. You should take prompt action to correct these violations. Failure to take appropriate corrective action may result in regulatory action, including seizure and/or injunction, without further notice.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should include each step taken or that will be taken to correct these violations and prevent recurrence. You should include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

Please send your reply to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer at the above address. If you have questions regarding any issues in this letter, please contact Mr. Ota at 781-587-7487.

Sincerely,
/S/
Mutahar S. Shamsi
District Director
New England District

Close Out Letter

- Island Desserts, LLC - Close Out Letter 7/13/12¹

Page Last Updated: 07/20/2012

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

[Accessibility](#) [Contact FDA](#) [Careers](#) [FDA Basics](#) [FOIA](#) [No Fear Act Site Map](#) [Transparency Website Policies](#)

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)

[Contact FDA](#)



[For Government](#) [For Press](#)

[Combination Products Advisory Committees](#) [Science & Research](#) [Regulatory Information](#) [Safety](#)
[Emergency Preparedness](#) [International Programs](#) [News & Events](#) [Training and Continuing Education](#)
[Inspections/Compliance](#) [State & Local Officials](#) [Consumers](#) [Industry](#) [Health Professionals](#) [FDA Archive](#)



Links on this page:

1. [/ICECI/EnforcementActions/WarningLetters/2011/ucm312747.htm](http://www.fda.gov/iceci/enforcementactions/WarningLetters/2011/ucm312747.htm)